

AMENDMENT TO H.R.**OFFERED BY MR. ALLEN**

(Page & line nos. refer to Committee Print of 6/13/03)

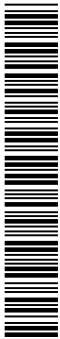
Insert at the appropriate place the following:

1 **SEC. ____.** **CMS RESEARCH AND STUDY ON EFFECTIVENESS**
2 **OF CERTAIN PRESCRIPTION DRUGS.**

3 (a) IN GENERAL.—The Administrator of the Centers
4 for Medicare & Medicaid Services (in this section referred
5 to as the “Administrator”)—

6 (1) shall provide for the conduct of research,
7 which may include clinical research, to develop valid
8 scientific evidence regarding the comparative effective-
9 tiveness, cost-effectiveness, and, where appropriate,
10 comparative safety of covered prescription drugs rel-
11 ative to other drugs and treatments for the same
12 disease or condition; and

13 (2) taking into consideration the research con-
14 ducted under paragraph (1), shall use evidence-
15 based practice centers to conduct studies or other
16 analyses of the comparative effectiveness, cost-effec-
17 tiveness, and, where appropriate, comparative safety
18 of covered prescription drugs relative to other drugs
19 and treatments for the same disease or condition.



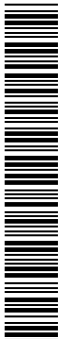
1 (b) SAFETY.—In any analysis of comparative effec-
2 tiveness or cost-effectiveness under subsection (a)(2), the
3 Administrator shall include a discussion of available infor-
4 mation on relative safety.

5 (c) STANDARDS.—The Administrator, in consultation
6 with the Director of the Agency for Healthcare Research
7 and Quality, the Commissioner of Food and Drugs, the
8 Director of the National Institutes of Health, and stake-
9 holders, shall develop standards for the design and con-
10 duct of cost-effectiveness studies under this subsection.

11 (d) COVERED PRESCRIPTION DRUGS.—For purposes
12 of this section, the term “covered prescription drugs”
13 means prescription drugs that, as determined by the Ad-
14 ministrator, account for high levels of expenditures or use
15 by individuals in Medicare.

16 (e) ANNUAL REPORTS.—Each year the Adminis-
17 trator shall prepare and submit to the Congress a report
18 on the results of the research, studies, and analyses con-
19 ducted under this section.

20 (f) REPORTS FOR PRACTITIONERS.—As soon as pos-
21 sible, but not later than a year after the completion of
22 any study under subsection (a)(2), the Administrator
23 shall—



1 (1) prepare a report on the results of such
2 study for the purpose of informing health care prac-
3 titioners; and

4 (2) publish the report on the Internet and
5 through other means that will facilitate access by
6 practitioners.

7 (g) EVIDENCE.—In carrying out this section, the Ad-
8 ministrator shall consider only methodologically sound
9 studies, giving preference to studies for which the Admin-
10 istrator has access to sufficient underlying data and anal-
11 ysis to address any significant concerns about method-
12 ology or the reliability of data.

13 (h) AGREEMENTS.—The Administrator may enter
14 into agreements with the Directors of the National Insti-
15 tutes of Health and the Agency for Healthcare Research
16 and Quality to carry out this section.

